## EnzymaticTherapy

NATURAL MEDICINES®

November 21, 2003



Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810 Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S) TO WHICH THE CLAIM REFERS
AM/PM PeriMenopause Formula™*	Easy Answers is a 3-Stage system for every woman's life! Each system includes a hormone-free, natural hormone balancer, a stage-specific multivitamin, targeted bone health support and relief for the uncomfortable symptoms of PMS, perimenopause and menopause.*	AM Formula: Black Cohosh Root Extract, Rhodiola Rosea 3%, Chaste Berry Extract, Green Tea Extract PM Formula: Hops Flower Extract, Black Cohosh Root and Rhizome Extract, L-Theanine, Valerian Root Extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By:	KIRBILL	
	Robert Doster Senior Vice President of Sc	cientific Affairs
Date:	11/21/03	

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AM/PM Perimenopause 49e

LET 13425 975 0162

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely

Michael P. Devereux Chief Financial Officer